

REMARKS

In this Amendment, Applicant has cancelled Claims 37 – 44 and Claims 59 – 66, without prejudice or disclaimer, and amended Claims 21 and 45. Claims 21 and 45 are amended to further specify the invention. It is respectfully submitted that no new matter has been introduced by the amended claims. All claims are now present for examination and favorable reconsideration is respectfully requested in view of the preceding amendments and the following comments.

REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH:

Claim 45 has been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

It is respectfully submitted that in view of presently claimed invention, the rejection has been overcome. Claim 45 has been amended to more clearly and thoroughly describe the subject matter of Applicant's invention. In particular, Claim 45 specifies that the compound is "biologically, chemically or pharmaceutically active" and "normally subject to deactivation on drying." In addition, it specifies that "the monosaccharide sugar alcohol and the additive being selected such that the composition solidifies as an amorphous glass irrespective of the presence or absence of the active compound." Therefore, one of ordinary skills in the art is able to reasonably understand the scope of the invention.

Accordingly, withdrawal of the rejection under 35 U.S.C. § 112 second paragraph is respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 102:

Claims 21 – 28, 33, 37 – 44, 46 – 50 and 55 have been rejected under 35 U.S.C. § 102 (b) as allegedly being anticipated by Foster et al. (US 6,258,341 B1), hereinafter Foster. Applicant respectfully submits that the present-claimed invention is not anticipated by the cited reference.

It is respectfully submitted that to satisfy the requirements of § 102, *each and every* element of a claimed invention must be found in the cited anticipative reference; it is insufficient that the corresponding element in the cited anticipative reference be “equivalent” to the element of the claimed invention. *Richardson v. Suzuki Motor Co.*, 868 F. 2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989). It is further respectfully submitted that in order to anticipate the presently claimed invention, a reference must contain all of the essential elements in the invention as claimed. *Lewmar Marine Inc. v. Bariant Inc.*, 827 F.2d 744, 3 USPQ 1766 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1007 (1988). Further, a reference that merely contains substantially the same elements is insufficient to “anticipate” the claimed invention. *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 756 F.2d 1556, 225 USPQ 253 (Fed. Cir. 1985).

The newly amended Claim 21 has included the limitation that “the composition of the solution being selected such that it solidifies as an amorphous glass irrespective of the presence or absence of the active compound.” Foster does not teach or suggest that an amorphous glass can be formed in the absence of the active compound. To the contrary, Foster requires that the active itself present in the composition for forming the amorphous glass (col. 13, lines 18 – 20). Especially, Foster discloses that the active itself is a natural glass former and present in high concentration comparing to the stabilizing mannitol (col. 15, lines 2 –3, and Examples 2 – 8). The choice of glass former depends on the characteristics of the actives (col. 13, lines 64 – 66). In addition, the compositions in Foster cannot be used in environments where only a small quantity active substance needs to be included in a manageable large quantity of injectable liquid. Due to the small amount of such active substance, the active substance cannot be in excessive of sugar alcohol to form glass. The present invention, however, can be used to form glass even without the active substance. The precise concentration of stabilizing glass-former

used is not critical as long as it is in excess. Therefore, the glass of the present invention is easily adaptable for using with different active substances.

In addition, Claim 21 has specified that the compound is “biologically, chemically or pharmaceutically active.” Applicant respectfully submits that Foster discloses only stabilizing the physical dispersion of power particles, which is different from the scope of the present invention for stabilizing biologically, chemically or pharmaceutically active compound. Other claims are also distinguishable from Foster due to their dependency on Claims 21 and 45.

Therefore, it is respectfully submitted that in view of presently claimed invention, the rejection has been overcome.

REJECTIONS UNDER 35 U.S.C. § 103:

Claims 21 – 66 have been rejected under 35 U.S.C. § 103, as allegedly being obvious and unpatentable over Foster et al. (US 6,258,341 B1), hereinafter Foster.

It is respectfully submitted that in view of presently claimed invention, the rejection has been overcome. As Examiner pointed out, Foster does not disclose the glass formers or additives as claimed in the present invention. More importantly, Foster does not teach or suggest that an amorphous glass can be formed in the absence of the active compound when the solution is selected from one or more monosaccharide sugar alcohol which would normally form sugar crystals on drying and at least one additive which is a glass-former or a formulation-facilitator. To the contrary, Foster teaches away from the present invention by requiring that the active itself be a natural glass former and present in high concentration comparing to the stabilizing mannitol (col. 15, lines 2 –3, and Examples 2 – 8). In Claim 36, Foster does not disclose the use of dextran in combination with mannitol. Nowhere in Foster disclose or suggest that an amorphous glass can be formed in the absence of the active compound by using dextran as a glass former. It is not obvious to a person of ordinary skill in the art to discern the present invention in which an amorphous glass can be formed in the absence of the active compound when the solution is selected from one or more monosaccharide sugar alcohol which would normally form sugar crystals on drying and at least one additive which is a glass-former or a formulation-facilitator.

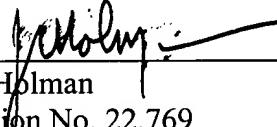
Therefore, Foster does not teach or suggest the present invention as in the Claims 21 – 66. Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §103 be withdrawn.

Having overcome all outstanding grounds of rejection, the application is now in condition for allowance, and prompt action toward that end is respectfully solicited.

Respectfully submitted,

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